

## § 26.155

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administrative or disciplinary proceeding against an individual when that proceeding is based on urinalysis results reported by the HHS-certified laboratory;

(3) The laboratory shall maintain test records in confidence, consistent with the requirements of § 26.37, and use them with the highest regard for individual privacy.

(4) Consistent with the principles established in section 503 of Public Law 100–71, any employee of a licensee or other entity who is the subject of a drug test (or his or her representative designated under § 26.37(d)) shall, on written request, have access to the laboratory's records related to his or her validity and drug test and any records related to the results of any relevant certification, review, or revocation-of-certification proceedings;

(5) The laboratory may not enter into any relationship with the licensee's or other entity's MRO(s) that may be construed as a potential conflict of interest, including, but not limited to, the relationships described in § 26.183(b), and may not derive any financial benefit by having a licensee or other entity use a specific MRO; and

(6) The laboratory shall permit representatives of the NRC and any licensee or other entity using the laboratory's services to inspect the laboratory at any time, including unannounced inspections.

(g) If licensees or other entities use a form other than the current Federal custody-and-control form, licensees and other entities shall provide a memorandum to the laboratory explaining why a non-Federal form was used, but must ensure, at a minimum, that the form used contains all the required information on the Federal custody-and-control form.

[73 FR 17176, Mar. 31, 2008, as amended at 74 FR 38328, Aug. 3, 2009]

### § 26.155 Laboratory personnel.

(a) *Day-to-day management of the HHS-certified laboratory.* HHS-certified laboratories shall have a responsible person to assume professional, organizational, educational, and administrative responsibility for the laboratory's drug testing facilities.

(1) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are as follows:

(i) Certification by the appropriate State as a laboratory director in forensic or clinical laboratory toxicology; or

(ii) A PhD in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, the responsible person shall also have the following minimum qualifications:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology (e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors that qualify the individual as an expert witness in forensic toxicology).

(2) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory, even if another individual has overall responsibility for an entire multi-specialty laboratory.

(3) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(4) This individual shall be responsible for ensuring that the laboratory has a manual of standard operating procedures that are complete, up-to-date, available for personnel performing tests, and followed by those

personnel. The procedures must be reviewed, signed, and dated by this responsible person whenever the procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory. This individual shall ensure that copies of all procedures and records of the dates on which they are in effect are maintained. (Specific contents of the procedures are described in § 26.157.)

(5) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; maintaining acceptable analytical performance for all controls and standards; maintaining quality control testing; and assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(6) This individual shall be responsible for taking all remedial actions that may be necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, including errors in result reporting or in the analysis of performance testing results. This individual shall ensure that test results are not reported until all corrective actions have been taken and he or she can assure that the test results provided are accurate and reliable.

(b) *Certifying scientist.* (1) HHS-certified laboratories shall have one or more certifying scientists who review all pertinent data and quality control results to certify the laboratory's test results.

(2) A certifying scientist shall be an individual with at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field who reviews all pertinent data and quality control results. The individual shall have training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain-of-custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies. Relevant training and experience must also include the review, interpretation,

and reporting of test results; maintenance of chain of custody; and proper remedial action to be taken in response to aberrant test or quality control results, or a determination that test systems are out of control limits.

(3) A laboratory may designate certifying scientists who only certify results that are reported negative and certifying scientists who certify results that are reported both negative and adulterated, substituted, dilute, or invalid.

(c) *Day-to-day operations and supervision of analysts.* HHS-certified laboratories shall assign one or more individuals who are responsible for day-to-day operations and supervision of the technical analysts. The designated individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field. The individual(s) shall also have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; review, interpretation, and reporting of test results; maintenance of the chain of custody; and proper remedial actions to be taken in response to aberrant test or quality control results, or the finding that test systems are out of control limits.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for their assigned tasks.

(e) *Training.* HHS-certified laboratories shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* At a minimum, each laboratory personnel file must include a résumé, any professional certification(s) or license(s), a job description, and documentation to show that the individual has been properly trained to perform his or her job.

#### § 26.157 Procedures.

(a) HHS-certified laboratories shall develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.